

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT** ( Not for submission under 37 CFR 1.99)

Application Number	10596725
Filing Date	2006-10-26
First Named Inventor	Susanne Alenfalk
Art Unit	1624
Examiner Name	Mark L. Berch
Attorney Docket Number	133087.10601 101342-1P US

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	2	5744467		1998-04-28	McKittrick et al.	
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	4	7253543		2007-06-26	Burnett et al.	

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	1	20080064676		2008-03-13	AstraZeneca AB	
	2	20070142304		2007-06-21	AstraZeneca AB	

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3	20030119757		2003-06-26	Schering Corp.	
4	20030119428		2003-06-26	Schering Corp.	
5	20040018060		2003-06-26	Schering Corp.	
6	20040018061		2004-01-29	Jansson	
7	20040254369		2004-12-16	Patel	
8	20050096307		2005-05-05	Schering Corp.	
9	20050267049		2005-12-01	Goulet et al.	
10	20060046996		2006-03-02	Nissan Chemical Ind Ltd.	
11	20060069080		2006-06-29	Incyte Corp.	
12	20070078098		2007-04-05	Merck and Co., Inc.	
13	20070129540		2007-06-07	Opus Organics Pvt Ltd.	

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14	20070049748		2007-03-01	Dr. Reddys Lab Ltd	
15	20070155675		2007-07-05	Burnett et al.	
16	20070155674		2007-07-05	Burnett et al.	

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	1	2005061452	WO		2005-07-07	AstraZeneca AB		<input type="checkbox"/>
	2	2005062824	WO		2005-07-14	Merck & Co. Inc.		<input type="checkbox"/>
	3	2006017257	WO		2006-02-16	Phenomix Corp.		<input type="checkbox"/>
	4	2005061451	WO		2005-07-07	AstraZeneca AB		<input type="checkbox"/>
	5	2005062897	WO		2005-07-14	Dr Reddys Lab Ltd		<input type="checkbox"/>
	6	2005066120	WO		2005-07-21	Ranbaxy Lab Ltd.		<input type="checkbox"/>

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7	2005069900	WO		2005-08-04	Merck & Co. Inc.		<input type="checkbox"/>
8	03026643	WO		2003-04-03	Schering Corp.		<input type="checkbox"/>
9	04043456	WO		2004-05-27	Schering Corp.		<input type="checkbox"/>
10	04043457	WO		2004-05-27	Schering Corp.		<input type="checkbox"/>
11	2005113495	WO		2005-12-01	Aventis Pharma GMBH		<input type="checkbox"/>
12	04099132	WO		2004-11-18	Ranbaxy Laboratories Limited		<input type="checkbox"/>
13	04107958	WO		2004-12-16	Schering Corp.		<input type="checkbox"/>
14	05000353	WO		2005-01-06	Kotobuki Pharmaceutical Co. Ltd.		<input type="checkbox"/>
15	2005021495	WO		2005-03-10	Microbia Inc.		<input type="checkbox"/>
16	2007075702	WO		2007-07-05	Schering Corporation		<input type="checkbox"/>
17	2005033100	WO		2005-07-25	Lipideon Biotechnology AG		<input type="checkbox"/>

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18	05042692	WO		2005-05-12	Forbes Medi Tech Inc.		<input type="checkbox"/>
19	2005113496	WO		2005-12-01	Aventis Pharma GMBH		<input type="checkbox"/>
20	2005044256	WO		2005-05-19	Merck & Co. Inc.		<input type="checkbox"/>
21	2005049592	WO		2005-06-02	Hetero Drugs Ltd.		<input type="checkbox"/>
22	2005047248	WO		2005-05-26	Microbia Inc.		<input type="checkbox"/>
23	2005058316	WO		2005-06-30	Sumitomo Pharma		<input type="checkbox"/>
24	1362855	EP		2003-11-19	Kotobuki Pharmaceutical Co. Ltd.		<input type="checkbox"/>
25	1413331	EP		2001-09-21	Schering Corporation		<input type="checkbox"/>
26	2007008529	WO		2007-01-18	Kalypsys, Inc.		<input type="checkbox"/>
27	2007008541	WO		2007-01-18	Kalypsys, Inc.		<input type="checkbox"/>
28	2007030721	WO		2007-03-15	Teva Pharmaceutical Industries Ltd. et al.		<input type="checkbox"/>

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29	2005067903	WO		2005-07-25	Panacea Boitec Ltd.	<input type="checkbox"/>
30	2005021497	WO		2005-03-10	Microiba, Inc.	<input type="checkbox"/>

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**NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	Notice of allowance dated July 31, 2008 for Application No. 10/519,897. (133087.07001)	<input type="checkbox"/>
	2	Office Action dated February 28, 2008 for Application No. 10/519,897. (133087.07001)	<input type="checkbox"/>
	3	Notice of allowance dated August 28, 2007 for Application No. 10/519,897. (133087.07001)	<input type="checkbox"/>
	4	Office Action dated May 1, 2007 for Application No. 10/519,897. (133087.07001)	<input type="checkbox"/>
	5	McKittrick et al., "Synthesis of C3 heteroatom-substituted azetidinones that display potent cholesterol absorptioninhibitory activity," (1998) 41(5):752-759.	<input type="checkbox"/>
	6	Clader et al., "2-Azetidinone Cholesterol Absorption Inhibitors: Structure-Activity Relationships on the HeterocyclicNucleus," J. Med Chem (1996) 39:3684-3693.	<input type="checkbox"/>
	7	McKittrick et al., "Stereoselective synthesis and biological activity of cis azetidinones as cholesterol absorptioninhibitors, Bioorganic & Medicinal Chemistry Letters (1996) 6(16):1947-1950.	<input type="checkbox"/>

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8	Burnett et al., "2-Azetidinones as Inhibitors of Cholesterol Absorption," J. Med Chem (1994) 12:1733-1736.	<input type="checkbox"/>
9	Castaner et al., "Ezetimibe Hypolipidemic, Cholesterol absorption inhibitor," Drugs of the Future (2000) 25(7):679-685.	<input type="checkbox"/>
10	Vaccaro et al., "Sugar-substituted 2-azetidinone cholesterol absorption inhibitors: Enhanced potency by modification of the sugar," Bioorganic & Medicinal Chemistry Letters (1998) 8:313-318.	<input type="checkbox"/>
11	Fu et al., "Process for preparing Ezetimibe intermediate by an acid enhanced chemo- and enantioselective CBS catalyzed ketone reduction," Tetrahedron Letters (2003) 44:801-804.	<input type="checkbox"/>
12	Kirkup et al., "(1)-SCH 57939: synthesis and pharmacological properties of a potent, metabolically stable cholesterol absorption inhibitor," Bioorganic & Medicinal Chemistry Letters (1996) 6(17):2069-2072.	<input type="checkbox"/>
13	Rosenblum et al., "Discovery of 1-(4-fluorophenyl)-(3R)-[3-(4-fluorophenyl)-(3S)-hydroxypropyl]-(4S)-(4-hydroxyphenyl)-2-azetidinone (SCH 58235): a designed, potent, orally active inhibitor of cholesterol absorption.," J. Med Chem (1998) 41:973-980.	<input type="checkbox"/>
14	Wu et al., "A Novel One-Step Diastereo- and Enantioselective Formation of trans-Azetidinones and Its Application to the Total Synthesis of Cholesterol Absorption Inhibitors," J. Org. Chem (1999) 64:3714-3718.	<input type="checkbox"/>
15	Dugar et al., "Gamma-lactams and related compounds as cholesterol absorption inhibitors: homologs of the beta-lactam cholesterol absorption inhibitor SCH 48461," Bioorganic & Medicinal Letters (1995) 5(24):2947-2952.	<input type="checkbox"/>
16	Mounsey et al., "Diet may slow progression of diabetic nephropathy," The Journal of Family Practice (2003) 52(9):672-673.	<input type="checkbox"/>
17	Sobieszczyk et al., "Acute pulmonary embolism: don't ignore the platelet," Circulation (2002) 106(14):1748-1749.	<input type="checkbox"/>
18	van Heek et al., "Comparison of the activity and disposition of the novel cholesterol absorption inhibitor, SCH58235, and its glucuronide, SCH60663," Br. J. Pharmacol (2000) 129(8):1748-1754.	<input type="checkbox"/>

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19	Yang et al., "Allelic Variants in Long-QT Disease Genes in Patients With Drug-Associated Torsades de Pointes,"Circulation (2002) 105(16):1943-1948.	<input type="checkbox"/>
20	Zaks et al., "Enzymatic glucuronidation of a novel cholesterol absorption inhibitor, Sch 58235, Appl BiochemBiotechnol. (1998) 73(2-3):205-214.	<input type="checkbox"/>
21	Clader "The discovery of ezetimibe: a view from outside the receptor," J Med Chem (2004 47(1):1-9.	<input type="checkbox"/>
22	Altmann et al., "Niemann-pick C1 like 1 protein is critical for intestinal cholesterol absorption," Science(2004) 303:1201-1204.	<input type="checkbox"/>
23	Notice of copending applications (2pp).	<input type="checkbox"/>
24	Journal of the American College of Cardiology (2000) 35(1):252A.	<input type="checkbox"/>
25	Kvaerno et al., "Synthesis and in vitro evaluation of inhibitors of intestinal cholesterol absorption," J Med Chem (2005) 48(19):6035-6053.	<input type="checkbox"/>
26	Burnett "Beta-lactam cholesterol absorption inhibitors," Curr Med Chem (2004) 11:1873-1887.	<input type="checkbox"/>
27	Seedorf et al., "Cholesterol absorption inhibitor ezetimibe blocks uptake of oxidized LDL in human macrophages," Biochem Biophys Research Commun (2004) 320(4):1337-1341.	<input type="checkbox"/>
28	Kvaerno et al., "An in vitro assay for evaluation of small-molecule inhibitors of cholesterol absorption," (2004) 43 (35):4653-4656.	<input type="checkbox"/>
29	Clader "Ezetimibe and other azetidinone cholesterol absorption inhibitors," Curr Topics in Med Chem (2005) 5 (3):243-256.	<input type="checkbox"/>



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30	Carcia-Calvo et al., "The target of ezetimibe is Niemann-Pick C1-Like 1 (NPC1L1)," PNAS (2005) 102(23):8132-8137.	<input type="checkbox"/>
31	Ritter et al., "Heterocyclic ring scaffolds as small-molecule cholesterol absorption inhibitors," Org Biomol Chem (2005) 3:3514-3523.	<input type="checkbox"/>

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Examiner Signature	/Mark Berch/ (07/14/2009)	Date Considered	
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